

# **DOE Regulatory Unit Evaluation Report of BNFL Inc.'s Quality Assurance Program and Implementation Plan**



January 7, 2000

Office of Safety Regulation of the TWRS-P Contractor

U.S. Department of Energy  
Richland Operations Office  
P.O. Box 550, A4-70  
Richland, Washington 99352

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Approved by: \_\_\_\_\_

Date: \_\_\_\_\_

## PREFACE

The U.S. Department of Energy's (DOE) Richland Operations Office (RL) issued a request for proposal in February 1996 for privatized processing of waste as part of the Hanford Tank Waste Remediation System (TWRS) program which in 1999 came under the cognizance of the Office of River Protection (ORP). Offerors were requested to submit proposals for the initial processing of the tank waste at the Hanford Site. Some of this radioactive waste has been stored in large underground storage tanks at the Site since 1944. Currently, approximately 54 million gallons of waste containing approximately 250,000 metric tons of processed chemicals and 215 million curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (Resource Conservation and Recovery Act).

Under the privatization concept, DOE intends to purchase waste processing services from a contractor-owned, contractor-operated facility through a fixed-price contract. DOE will provide the waste feedstock for processing but maintain ownership of the waste. The contractor must: (a) provide private financing; (b) design the equipment and facility; (c) apply for and receive required permits and licenses; (d) construct the facility and commission its operation; (e) operate the facility to process tank waste according to DOE specifications; and (f) deactivate the facility.

The TWRS Privatization (TWRS-P) Project is divided into two phases, Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort. The objectives of Phase I are to (a) demonstrate the technical and business viability of using privatized contractors to process Hanford tank waste; (b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; (c) maintain environmental protection and compliance; and (d) substantially reduce life-cycle costs and time required to process the tank waste. The Phase I effort consists of three parts: Part A, Part B-1, and Part B-2.

Part A, which concluded in August 1998, was a twenty-month period to establish technical, operational, regulatory, and financial elements necessary for privatized waste processing services at fixed-unit prices. This included identification by the TWRS-P Contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the Contractors and evaluation by DOE of initial safety assessments. Of the twenty-month period, sixteen months was for the Contractors to develop the Part A deliverables and four months was for DOE to evaluate the deliverables and determine whether to authorize Contractors to perform Part B. Part A culminated in DOE's authorization on August 24, 1998, of BNFL Inc. to perform Part B-1.

Part B-1 is a twenty-four month period to (a) further the waste processing system design introduced in Part A, (b) revise the technical, operational, regulatory, and financial elements established in Part A, (c) provide firm fixed-unit prices for the waste processing services, and (d) achieve financial closure.

Part B-2 is a sixteen-year period to complete design, construction, and permitting of the privatized facilities; provide waste processing services for representative tank wastes at firm fixed-unit prices; and deactivate the facilities. During Part B-2, approximately 10% by volume (25% by activity) of the total Hanford tank wastes will be processed.

Phase II will be a full-scale production effort. The objectives of Phase II are to implement the lessons learned from Phase I and to process all remaining tank waste into forms suitable for final disposal.

An essential element of the TWRS-P Project is DOE's approach to safety regulation. DOE has specifically defined a regulatory approach and chartered a dedicated Office of Safety Regulation of the TWRS-P Contractor (Regulatory Unit). The DOE aim in proceeding with the safety regulation of the TWRS-P contractor is to establish a regulatory environment that will permit privatization to occur on a timely, predictable, and stable basis. In addition, attention to safety must be consistent with that which would accrue from regulation by external agencies. DOE is patterning its radiological and nuclear safety regulation of the TWRS-P contractor to be consistent with that of the U.S. Nuclear Regulatory Commission (NRC). For industrial hygiene and safety (IH&S), regulation is consistent with that of the Occupational Safety and Health Administration (OSHA).

The RL Manager has responsibility and authority for safety regulation and has assigned this authority to the RL Director of the TWRS-P Regulatory Unit (the Regulatory Official). This regulatory authority is exclusive to the regulation of the TWRS-P contractor. The Regulatory Official is the formal point of execution for safety regulation of the TWRS-P contractor.

The DOE requires the contractor to integrate safety into all facets of work planning and execution. This Integrated Safety Management (ISM) process emphasizes that it is the contractor's direct responsibility for ensuring that safety is an integral part of mission accomplishment. Like the approach taken by the NRC and OSHA, the privatized contractor has primary responsibility for safety. The DOE, through its program, is responsible for ensuring that the contractor establishes and complies with approved safety limits.

The relationship between DOE and the privatized contractor performing work under a fixed-price contract is different than the relationship under traditional Management and Operations (M&O) contracts. For fixed-price contracting to be successful, this different safety relationship with the contractor is accompanied by modified relationships among DOE's internal organizations. For example, the arrangement by which the RL Manager applies regulation to the TWRS-P contractor should be a surrogate for an external regulator (such as the NRC or OSHA) with strong emphasis on independence, reliability, and openness.

Regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the Contractor from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

**All documents issued by the Office of Safety Regulation of TWRS-P Contractor are available to the public through the DOE/RL Public Reading Room at the Consolidated Information Center, Room 1012, Richland, Washington. Copies may be purchased for a duplication fee.**

## RECORD OF REVISION

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## Executive Summary

This report documents the results of the Regulatory Unit's (RU's)<sup>1</sup> review of the annual revision of BNFL Inc.'s (BNFL's) Quality Assurance Program and Implementation Plan (QAPIP), BNFL-5193-QAP-01.

On May 27, 1999, BNFL submitted to the RU changes resulting from its annual review of the current revision of the QAPIP (Revision 4).<sup>2</sup> This modified QAPIP (Revision 4A) was provided to the RU, as required by the TWRS-P Contract,<sup>3</sup> with the intent that upon RU approval BNFL would issue the document as QAPIP Revision 5. In response to RU reviews, BNFL submitted two additional versions of the QAPIP, Revisions 4B and 4C. The RU reviewers conducted the reviews of the revised BNFL QAPIPs using RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program* and G-830.120, *Implementation Guide For Use With 830.120 Quality Assurance*.

The reviewers found that the proposed BNFL QAPIP Revision 4C complies with applicable quality assurance regulations and related guidance, and meets the requirements imposed by the BNFL Contract for design activities. The reviewers also noted that changes proposed by BNFL QAPIP Revision 4C will necessitate changes to the TWRS-P Project Integrated Safety Management Plan (BNFL-5193-ISP-01, Revision 4).

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<sup>1</sup> The official organization title is Office of Safety Regulation of the Tank Waste Remediation System Privatization (TWRS-P) Contractor.

<sup>2</sup> 99-RU-0337, Letter, C. Burrows, BNFL Inc., to D. C. Gibbs, RL, "TWRS Privatization Contract No. DE-AC06-96RL13308 - W375 - Quality Assurance Program and Implementation Plan (BNFL-5193-QA-01, Rev. 4A)," dated May 27, 1999.

<sup>3</sup> Contract No. DE-AC06-96RL13308, between DOE and BNFL Inc., dated August 24, 1998.

<sup>4</sup> Upon RU approval, BNFL will issue Revision 4C as Revision 5.

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# **DOE Regulatory Unit Evaluation Report of BNFL Inc.'s Quality Assurance Program and Implementation Plan (QAPIP)**

## **1.0 Introduction and Purpose**

BNFL Inc. (BNFL) is required by Contract<sup>5</sup> to meet the requirements of 10 CFR 830.120, "Quality Assurance Requirements." These requirements state the following:

"The contractor may, at any time, make changes to an approved QAP [Quality Assurance Program]. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of the section."

In its currently approved QAPIP, Revision 4, dated May 1998, BNFL committed to the following:

"Changes to the QAP and Implementation Plan that affect commitments specified in a previously approved QAP and Implementation Plan shall be submitted to the RU for review and approval 30 days before implementation of the subject changes."

The purposes of this evaluation report are as follows:

- Describe the RU review process.
- Describe the BNFL submittals.
- Document the BNFL response to RU review findings.
- Document the conclusions of the RU review process.

All letters and documents referenced in this evaluation report are in the public record and are available through the U.S. Department of Energy, Richland Operations Office Public Reading Room at the Consolidated Information Center, 2710 University Drive, Richland, Washington.

## **2.0 Review Process**

### **2.1 Review Approach for the QAPIP**

The RU assembled a three-person review team to evaluate BNFL's QAPIP. The review team composition and expertise are presented in Section 2.3 of this report. In addition, Mr. J. G. Spraul of the U.S. Nuclear Regulatory Commission (NRC) provided valuable input and comments on the QAPIP for review team consideration.

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<sup>5</sup> Contract No. DE-AC06-96RL13308, Standard 4, "Safety Health and Environmental Program."

The reviewers systematically evaluated BNFL's QAPIP using guidance established in the following documents:

10 CFR 830.120, "QUALITY ASSURANCE REQUIREMENTS"

- G-830.120, *Implementation Guide For Use With 10 CFR Part 830.120 Quality Assurance*
- RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*.

## **2.2 Review Chronology**

The chronology of the BNFL submittals and the RU review is shown in Section 3.2, Table 1.

## **2.3 Team Composition and Expertise**

The names, level of education, and expertise of the QAPIP review team are shown in Section 3.2, Table 2.

# **3.0 Findings**

## **3.1 Review of Revision 4A of the QAPIP**

The RU's approach to evaluating QAPIP Revision 4A included meeting with BNFL on several occasions to discuss the BNFL proposed changes and the reasons for the changes. The RU noted that the BNFL written rationale for the proposed changes did not fully document reasons for the changes or the basis for concluding that the changes continued to satisfy the requirements of 10 CFR 830.120. The RU reviewers generated 68 comments in evaluating Revision 4A. The RU considered 25 of the comments significant and the remainder "minor," primarily editorial. The significant comments and the BNFL response to the comments are provided as Appendix A to this document.

## **3.2 Review of Revision 4B of the QAPIP**

On August 9, 1999, BNFL provided their response to the RU comments on Revision 4A and provided QAPIP, Revision 4B. The RU's preliminary review of QAPIP Revision 4B identified a number of potentially significant issues, including the following:

- Many changes to the QAPIP were not associated with RU comments and represented new or revised BNFL commitments.
- Text previously agreed to and commented on by the RU had been deleted.

- Requirements from the Office of Civilian Radioactive Waste Management, DOE/RW-0333P, *Quality Assurance Requirements and Description for Civilian Radioactive Waste Management Program*, were introduced (in Revision 4A) and then removed (in Revision 4B).
- The document had been reorganized.

In a letter to BNFL, dated August 18, 1999, the RU documented these issues and formally rejected QAPIP Revision 4A according to 10 CFR 830.120, Part (b)(4). (This formal rejection was required because BNFL had not withdrawn Revision 4A.) On October 12, 1999, BNFL withdrew Revision 4B; and the RU stopped its review of the document without preparing additional formal comments.

**Table 1. Review Chronology for QAPIP**

Activity	Date
Revision 4A received from BNFL <sup>a</sup>	May 27, 1999
Comments on Revision 4A received from NRC <sup>b</sup>	June 22, 1999
RU written comments on Revision 4A provided to BNFL <sup>c</sup>	July 12, 1999
Response to RU comments on Revision 4A, rationale for changes to Revision 4, and Revision 4B received from BNFL <sup>d</sup>	August 9, 1999
RU letter rejecting Rev. 4A and providing potentially significant issues for preliminary review of Rev. 4B <sup>e</sup> provided to BNFL	August 18, 1999
BNFL letter received, withdrawing Revision 4B and providing Revision 4C with rationale for changes <sup>f</sup>	October 12, 1999
Comments on Revision 4C received from NRC <sup>g</sup>	November 3, 1999
RU written comments on Revision 4C provided to BNFL <sup>h</sup>	December 3, 1999
Response to RU comments on Revision 4C received from BNFL <sup>i</sup>	January 5, 2000
<sup>a</sup> 99-RU-0337, Letter, C. Burrows, BNFL Inc., to D. C. Gibbs, RL, "TWRS Privatization Contract No. DE-AC06-96RL13308 - W375 - Quality Assurance Program and Implementation Plan (BNFL-5193-QA-01, Rev. 4A)," dated May 27, 1999. <sup>b</sup> 99-RU-0396, Letter, R. C. Pierson, BNFL Inc., to D. C. Gibbs, RL, "Comments On The BNFL Inc. Quality Assurance Program and Implementation Plan," dated June 22, 1999. <sup>c</sup> 99-RU-0411, Letter, D. C. Gibbs, RL, to M. J. Lawrence, BNFL Inc., "Comments on "Quality Assurance Program and Implementation Plan" (BNFL-5193-QAP-01, Rev. 4A)," dated July 12, 1999. <sup>d</sup> 99-RU-0471, Letter, C. Burrows, BNFL Inc., to D. C. Gibbs, RL, "Contract No. DE-AC06-96RL13308 - W375 - Comments Resolution of Quality Assurance Program and Implementation Plan (BNFL-5193-QAP-01, Rev. 4A) and Revised Quality Assurance Program and Implementation Plan (BNFL-5193-QAP-01, Rev. 4B)," dated August 9, 1999. <sup>e</sup> 99-RU-0495, Letter, D. C. Gibbs, RL, to M. J. Lawrence, BNFL Inc., "BNFL Inc. (BNFL) Quality Assurance Program and Implementation Plan (QAPIP), dated August 18, 1999. <sup>f</sup> 00-RU-0013, Letter, A. Dobson, BNFL Inc., to D. C. Gibbs, RL, "Contract No. DE-AC06-96RL13308 - W375 - Quality Assurance Program and Implementation Plan (BNFL-5193-QAP-01) - Response to RU Concerns on Quality Assurance Program and Implementation Plan (BNFL-5193-QAP-01, Rev. 4B)," dated October 12, 1999. <sup>g</sup> 00-RU-0062, Letter, R. C. Pierson, BNFL Inc., to D. C. Gibbs, RL, "Comments On Revision 4C of the BNFL Inc. Quality Assurance Program and Implementation Plan," dated November 3, 1999. <sup>h</sup> 00-RU-0070, Letter, D. C. Gibbs, RL, to M. J. Lawrence, BNFL Inc., "Quality Assurance Program and Implementation Plan (QAPIP) Rev. 4C," dated December 3, 1999. <sup>i</sup> 00-RU-0161, Letter, A. Dobson, BNFL Inc., To D. C. Gibbs, RL, "Contract No. DE-AC06-96RL13308 - W375 - Submittal of the Revised Quality Assurance Program and Implementation Plan (BNFL-5193-QAP-01, Rev. 4C) for Department of Energy - Regulatory Unit Review and Approval" dated January 5, 2000.	

**Table 2. Education and Expertise of the QAPIP Review Team**

<b>Team Member</b>	<b>Education/Expertise</b>
Albert Hawkins	B.S. Chemical Engineering, MBA; more than 25 years experience in operations, oversight, safety, and quality assurance; former Manager of Compliance Assurance and Director of Environment, Safety, Health and Quality Assurance.
Thomas Colandrea, P.E.	B.S. Metallurgical Engineering; M.S. Engineering Science and Metallurgy, MBA, P.E. (California); ASQ Certified Quality Engineer, Reliability Engineer, and Quality Auditor; ANSI/ASME NQA-1 Lead Auditor; ISO 9000 Certified Lead Auditor; ASQ Fellow; 35 years experience in Nuclear QA and metallurgical engineering.
Cindy Taylor	B.A. in Business Management; MBA in Engineering Management and Technology; ANSI/ASME NQA-1 Lead Auditor; ISO 9000 Certified Lead Assessor; 20 years experience in nuclear, environmental, and analytical quality assurance.
John Spraul (NRC)	B.S. Chemical Engineering; Professional Designation in QC, UCLA; ASQ Senior Member and Certified Quality Engineer; former Chief Inspector and Director of Quality Assurance; 25 years experience in NRC's QA program.

### 3.3 Review of Revision 4C of the QAPIP

The BNFL letter of October 12, 1999, which withdrew Revision 4B, also transmitted Revision 4C for RU review. The RU performed a complete evaluation of Revision 4C using the approach described in Section 2.1 above. The RU also met with BNFL on several occasions to discuss issues and to resolve comments. Each comment was addressed individually. The BNFL response to the RU's comments reflects the extensive discussions and was formally provided on January 5, 2000, after the discussions were complete. The RU evaluated the formal BNFL submittal and found it consistent with our discussions and acceptable.

The full set of RU comments and BNFL responses is provided as Appendix B. To maintain consistency with the way the comments were discussed with BNFL, the RU did not separate editorial comments from substantive comments; a large number of the Appendix B comments are editorial.

## 4.0 Recommendations

### 4.1 Recommendation for Approval

The reviewers recommend that the Regulatory Official approve the QAPIP, subject to the conditions identified in Section 4.2. This recommendation is based on the following determinations:

- The QAPIP complies with 10 CFR 830.120, “Quality Assurance Requirements,” for the work that will be conducted up to start of construction of the TWRS-P Waste Treatment (WTP) facility.
- The QAPIP is consistent with the guidance established in G-830.120 and in RL/REG-96-01 for work that will be conducted up to start of construction of the TWRS-P WTP facility.
- The QAPIP meets the requirements of DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*.<sup>6</sup>
- The QAPIP recognizes the commitment identified in the Contract regarding the application of DOE/RW-0333P, *Quality Assurance Requirements and Description for Civilian Radioactive Waste Management Program*.

## 4.2 Conditions of Approval

The review team recommends that the following conditions be included with the approval of the BNFL QAPIP:

- BNFL shall implement the BNFL 5193-QAP-01, Revision 5,<sup>7</sup> as approved by the RU, for Part B activities up to the start of construction.
- BNFL shall modify the TWRS-P Project Integrated Safety Management Plan (BNFL-5193-ISP-01, Revision 4) as necessary to reflect the changes to the QAPIP.

## 5.0 References

10 CFR 830.120, “Quality Assurance Requirements,” *Code of Federal Regulations*, as amended.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, Rev. 1, U.S. Department of Energy, Richland Operations Office, 1998.

DOE/RW-0333P, *Quality Assurance Requirements and Description for Civilian Radioactive Waste Management Program*, Rev. 8, U.S. Department of Energy, 1997.

*Implementation Guide for Use with 10 CFR 830.120, Quality Assurance*, G-830.120, Rev.0, U.S. Department of Energy, 1994.

*Quality Assurance Program and Implementation Plan*, BNFL-5193-QAP-01, Rev. 4, BNFL Inc., 1998.

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<sup>6</sup> Section 4.1.6, “Quality Assurance.”

<sup>7</sup> Upon RU approval, BNFL will issue Revision 4C, as modified to respond to RU comments, as Revision 5.

RL/REG-96-01, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*, Rev. 0, U.S. Department of Energy, Richland Operations Office, 1998.